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PTO/SB/05 (4/98)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. CONFO.49060

First Inventor or Application Identifier John A. Macoviak

Title See 1 in Addendum

Express Mail Label No. EL631725709US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Specification [Total Pages 46]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the invention
 - Brief Summary of the invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 11]
4. Oath or Declaration [Total Pages 3]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

5. ☐ Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. ☐ Assignment Papers (cover sheet & document(s))
8. ☐ 37 C.F.R. § 3.73(b) Statement of Power of Attorney (when there is an assignee)
9. ☐ English Translation Document (if applicable)
10. ☒ Information Disclosure Statement (IDS)/PTO-1449 ☒ Copies of IDS Citations
11. ☐ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. ☒ * Small Entity Statement(s) ☐ Statement filed in prior application
(PTO/SB/09-12) Status still proper and desired
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☐ Other: _____

NOTE FOR ITEMS 1 & 13 IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. _____

Prior application information: Examiner _____

Group / Art Unit: _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label

or ☒ Correspondence address below

(Insert Customer No. or Attach bar code label here)

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Signature		Date	9/20/00

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Patent fees are subject to annual revision.
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See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT (\$)**762.00**

Complete if Known

Application Number
Filing Date
First Named Inventor **John A. Macoviak**
Examiner Name
Group / Art Unit
Attorney Docket No. **CONFO.49060**

METHOD OF PAYMENT (check one)

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

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Deposit Account Name

☒ Charge Any Additional Fee Required
Under 37 CFR §§ 1.16 and 1.17

2. ☒ Payment Enclosed:

☒ Check ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Code (\$)	Small Entity Code (\$)	Fee Description	Fee Paid
101 690	201 345	Utility filing fee	345.00
106 310	206 155	Design filing fee	
107 480	207 240	Plant filing fee	
108 690	208 345	Reissue filing fee	
114 150	214 75	Provisional filing fee	

SUBTOTAL (1) (\$)**345.00**

2. EXTRA CLAIM FEES

Total Claims	Extra Claims	Fee from below	Fee Paid
49	29	9	261
7	4	39	156
Multiple Dependent			0

**or number previously paid, if greater, For Reissues, see below

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description
103 18	203 9	Claims in excess of 20
102 78	202 39	Independent claims in excess of 3
104 260	204 130	Multiple dependent claim, if not paid
109 78	209 39	** Reissue independent claims over original patent
110 18	210 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)**417.00**

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath	0.00
127 50	227 25	Surcharge - late provisional filing fee or cover sheet.	0.00
139 130	139 130	Non-English specification	0.00
147 2,520	147 2,520	For filing a request for reexamination	0.00
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	0.00
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	0.00
115 110	215 55	Extension for reply within first month	0.00
116 380	216 190	Extension for reply within second month	0.00
117 870	217 435	Extension for reply within third month	0.00
118 1,360	218 680	Extension for reply within fourth month	0.00
128 1,850	228 925	Extension for reply within fifth month	0.00
119 300	219 150	Notice of Appeal	0.00
120 300	220 150	Filing a brief in support of an appeal	0.00
121 260	221 130	Request for oral hearing	0.00
138 1,510	138 1,510	Petition to institute a public use proceeding	0.00
140 110	240 55	Petition to revive - unavoidable	0.00
141 1,210	241 605	Petition to revive - unintentional	0.00
142 1,210	242 605	Utility issue fee (or reissue)	0.00
143 430	243 215	Design issue fee	0.00
144 580	244 290	Plant issue fee	0.00
122 130	122 130	Petitions to the Commissioner	0.00
123 50	123 50	Petitions related to provisional applications	0.00
126 240	126 240	Submission of Information Disclosure Stmt	0.00
581 40	581 40	Recording each patent assignment per property (times number of properties)	0.00
146 690	246 345	Filing a submission after final rejection (37 CFR § 1.129(a))	0.00
149 690	249 345	For each additional invention to be examined (37 CFR § 1.129(b))	0.00
Other fee (specify) _____			0.00
Other fee (specify) _____			0.00

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)**0.00**

SUBMITTED BY

Name (Print/Type)	Vern Schooley Esq.	Registration No. (Attorney/Agent)	24,649	Complete (if applicable)
Signature		Telephone	432-0453	Date
			9/20/00	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: John A. Macoviak

Serial No.:

Filed on:

Title: HEART VALVE ANNULUS DEVICE AND METHOD OF USING SAME

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(b)—INDEPENDENT INVENTOR

As a below named inventor, I hereby state that I qualify as an independent inventor, as defined in 37 CFR 1.9(c), for purposes of paying reduced fees to the United States Patent and Trademark Office under Sections 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office, with regard to the invention described in the specification filed herewith, with title as listed above.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c), if that person had made the invention, or to any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

No person, concern or organization exists to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

John A. Macoviak

Signature of Inventor

Date

9-5-00

HEART VALVE ANNULUS DEVICE AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a prosthetic heart valve anchor and a minimally invasive method for implantation.

Description of the Prior Art

It has been estimated that up to 20% of all cardiac surgeries are directly related to valve replacement or implantation of artificial valves. It is well known that a variety of medical conditions and diseases may cause damage to the heart valve which ultimately necessitates valve replacement. Certain diseases such as rheumatic fever can cause the valve orifice to shrink or pull apart. If these defects are not corrected, prolonged valvular stenosis or insufficiency may cause damage to the heart muscle and may even require complete valve replacement. Other indications, including congenital anomalies and myocardial infarction, may necessitate total valve replacement as well.

When complete valve replacement is necessary, the surgeon may choose from two types of prosthetic valves, mechanical or tissue valves. Mechanical valves are generally made from some type of rigid metal or hard plastic. They have been known to be formed from titanium coated with a pyrolytic carbon with polymer and biocompatible cloth covered sewing rings. Most of these currently available mechanical valves are either of a pivoting bi-leaflet or tilting mono-leaflet design. However, more flexible or elastic valves may be achieved using synthetic polymers which simulate a biological tissue valve.

Tissue valves, in contrast, consist of chemically preserved or cryopreserved animal tissue including human homografts and xenografts usually extracted from a pig or cow and typically mounted on a supporting frame known as a "valve stent". The valve stent itself is constructed from a metal and polymer material and covered with a biocompatible cloth material. A sewing ring is then used to tether the valve to the annulus. The sewing ring is typically a tubular synthetic structure which is designed to allow passage of the suture through the sewing ring in order to tether the valve. The sewing ring may be comprised of a biocompatible cloth which covers a silicone sewing ring and further having three valve stent commissure posts which project upward from the cloth and which serve to hold the three tissue leaflets of the valve in proper placement. Additionally, the valve stent provides a structural integrity which enables the surgeon to insert and mount the valve into the heart and suture it into place. These tissue valves are inherently advantageous because they are less likely to cause thrombosis, thereby reducing

the necessity of having the patient treated with anticoagulants. However the failure rate of these bioprosthetic valves is at 15% by fifteen years after surgery, and therefore these tend to require periodic replacement.

While heart valve implants have become widely accepted in the medical field, this procedure is still extremely costly. The medical personnel necessary for the procedure must comprise a skilled surgeon, perfusionist, anesthesiologist and a full operating room staff, as well as equipment which include a sophisticated heart/lung bypass machine. In addition to the expensive personnel, valve implant surgery requires extensive operating time which is both costly and subjects the patient to a greater health risk the longer he is on a bypass machine and under anesthesia.

It is the generally accepted practice in the medical field to implant prosthetic heart valve devices by means of surgical suturing of the valve into the heart. Valve designs currently on the market make the suturing technique advantageous because they permit direct securing of the valve with precise and easy visualization of the suture line. While there are a variety of advantages to this standard means of sewing the heart valve into orthotopic or heterotopic positions, there still remain a vast number of disadvantages which make an alternative means desirable to find. The sewing ring used to suture the valve into the patient's heart occupies a significant annulus area and therefore effectively reduces the amount of valve orifice area.

Furthermore, suture placement itself can be a tedious process which often demands a significant portion of the overall operation time. This is especially true in the case of younger or small patients as well as those patients who have undergone repeat procedures. Based on the need to reduce the overall length of time a patient undergoes surgery, one can appreciate that reduced suturing time or removal of the suturing process altogether is highly advantageous.

In addition, the accepted practice of hand suturing traditional prosthetic heart valves into place requires large open access to the chest cavity to enable the surgeon to precisely suture the valve into the heart muscle. Access is usually made through the open chest and a longitudinal incision in the ascending aorta is typically utilized for handheld instruments utilized for both valve placement and suturing. Accurate placement and orientation of the valve within the heart is a difficult and high risk aspect of this procedure which may be minimized by enlarging the chest openings, giving the surgeon better access and increasing the prospect that the valve will be placed successfully. For most cardiovascular surgeries, the need for precise suturing for securement of the heart valve prosthetic has been difficult to improve upon.

Therefore, while adequate access to the chest cavity has been considered necessary during heart valve replacement, it is an extremely traumatic event for the patient and subjects them to a higher risk of infection. Thus it can be appreciated that the need exists for a heart valve prosthetic that is subject to placement using minimally invasive surgical techniques.

Additionally, suturing the prosthesis valve into the heart muscle creates a subsequent problem for the patient due to the fact that the valve itself is bulky, and when sutured into place, the suturing process necessarily reduces the cross section of the flow path through the valve body. Such a flow restriction may adversely affect blood flow which may increase the transvalvular pressure gradients of the heart thereby requiring it to work harder to pump the same volume of blood. For a patient already experiencing heart stress, the increased pressure on the heart is clearly undesirable.

In addition to the restriction within the heart valve itself, narrowing of the valve structure is often brought on by the surgeon pulling the sutures as snugly as possible during placement of the prosthetic. The more snugly the valve fits the better. However, the result is that the tissue becomes constricted at the site of the implant. Another problem with the suturing technique is a tendency to constrict the heart annulus. Constrictions occur when sutures draw the heart annulus upwardly toward the valve sewing ring thereby drawing it partially into the annular opening of such sewing ring. Other problems associated with suturing of the valve prosthetic occur when the suture is placed too deeply into the muscle wall. When the suture extends deep into the muscle wall, the suture can catch the back wall of a contiguous structure thereby causing damage to that tissue or otherwise injuring the cardio-conduction system which may result in conduction abnormalities. Similarly, the relationship between the leaflets and the cloth covering

of the stent in biological tissue valves promotes pannus fibrosing tissue depositing, which eventually creeps inward from the periphery of the valve.

Similarly, sutures securing a valve in place may cause the formation of blood clots due to the presence of additional foreign objects in the body. The danger caused by these blood clots can be severe if a clot breaks away and enters the patient's blood stream, thereby causing a major health problem such as a heart attack or stroke. Additionally, the very nature of sutures creates problems because when the surgeon stitches the sew cuff in place, he or she knots and cuts the thread leaving raw edges somewhat exposed to the patient's blood stream. These raw edges create another area of potential blood clot formation and infection. Due to the location of these potential blood clots, a formed clot may even extend into the valve itself thus trapping it open or shut and generally causing overall valve malfunctions. It has been the general practice to administer an anti-coagulant such as heparin or warfarin to post-surgical patients in an attempt to reduce this potential for blood clotting. However, it can be appreciated that a valve prosthetic, which itself does not produce blood clots, is a safer and overall better alternative than administration of a blood thinning drug. It has also been observed that the presence of foreign materials in the body, such as sutures and staples, increases the potential for bacterial infection at that site. Therefore the benefit of reducing the suture requirement becomes apparent.

While there is an obvious need to provide a sutureless heart valve prosthetic, such a valve must also still fit snugly and securely in the heart annulus. Without a secure fit between the prosthetic and the tissue, leaks may develop between the valve anchor and heart annulus thereby allowing blood to bypass the valve. Such a situation may be disastrous. Therefore, while a need exists to find a viable alternative to suturing, the valve anchor must securely attach to the heart muscle without exhibiting leakage.

Many efforts have been made over the years to provide a satisfactory anchoring ring for a prosthetic valve and a tool for placement thereof. One such effort focused on the problems associated with suturing. A cuff was proposed having an exterior fabric skirt connected therewith to be stapled to the native annulus to anchor the cuff in position. A rather elaborate tool was proposed for implanting the cuff and stapling the skirt to the annulus. Devices of this type are shown in U.S. Patent No. 5,716,370 to Williamson et al. Such devices, while offering interesting solutions, are relatively complex and have not gained general acceptance in the field. Furthermore, the use of staples instead of sutures has been known to exhibit similar scarring and tension effects.

Another effort to create a secure valve holder which is also capable of reducing potential damage to the heart tissue was proposed as an assembly including a heart valve having a plurality of radially inwardly deflectable supports and a holder having inner and outer members

for suture attachment and to ensure a counterbalancing of the suture tension. A device such as this is disclosed in U.S. Patent No. 4,865,600 to Carpentier et al. While relatively effective in solving certain problems, such an assembly is fairly large and cumbersome as well as being mechanically complex.

5 Other devices for implanting a heart valve have been proposed which include a fork shaped tool having projecting tines which are flexibly mounted and formed on their distal ends with hooks which may be spread radially outwardly to releasably hook into the interior of the cuff and be biased in position by a removable biasing spring which may be removed after implantation. A device of this type is shown in U.S. Patent No. 5,236,450 to Scott. A device of
10 this nature, while effective to grip a conventional cuff, does not provide for mechanical anchoring of the cuff to the annulus or provide for an arrangement for deployment of a mechanically anchoring device.

 Therefore, it is clear that the need exists for a novel heart valve placement system which permits the surgeon to quickly, easily and securely implant the heart valve into the patient
15 with minimal resulting trauma to the patient and yet which is simple to construct and use and which achieves a high level of success.

SUMMARY OF THE INVENTION

The prosthetic valve anchor of the present invention may be implanted with mechanical retainers anchoring it facilitate the anchoring procedure. In some embodiments, separate suture eyes may be provided so that, once mechanically anchored in place, a selected number of supplemental sutures may be made to further facilitate anchoring. The anchor ring may incorporate a mounting arrangement for removably mounting an occluder thereto. This mounting arrangement, in some instances, is universal in that it will accept occluders manufactured by different manufacturers such that the single anchor ring will anchor different models of occluders. The anchor mechanism may be of the screw type, a rail fastener, a bayonet style engagement or any other type of mounting device as known to those skilled in the art. In one embodiment, the occluder may be removed with the anchor left in place. The anchor then cleaned up and a replacement occluder inserted without removal of the anchor.

In another embodiment, the prosthetic valve anchor may be formed by a ring device to be positioned in the opening of the heart annulus and having mechanically deployable mechanical retainer elements projectable radially outwardly to engage under the shelf of the heart annulus to anchor it in position. In one embodiment, the anchoring elements are formed integral with the ring and the ring is compressible axially to deploy such elements radially outwardly. In another embodiment, the anchor device includes a pair of interfitting rings which are rotatable

relative to one another and mount therebetween a retaining mechanism operable upon rotation of such rings relative to one another to project such retainers radially outwardly under such shelf.

The deployment tool includes an elongated tube mounting at its distal extremities with radially outwardly diverging tines for releaseable engagement on one location with the anchoring ring or rings and having a wire telescoped therethrough and mounting at its distal end an actuating fork having tines for engagement on a second location of such anchoring ring or rings. The wire is shiftable relative to the legs so that the tines may be manipulated relative to the tube to thereby shift the portions of the anchoring ring or rings relative to one another to deploy the retainers radially outwardly under the annulus shelf.

The method of the present invention involves accessing the patient's heart annulus and securing the anchor device to a deployment tool to introduce it to the heart annulus and deploy the retainer elements.

As can be seen, the heart valve anchor of the present invention takes advantage of mechanical retainers to minimize the time consuming process of suturing the valve anchor into place, thereby greatly reducing the overall time necessary to complete the surgical procedure. Such anchor offers the advantage that it can be implanted separate and independent of the occluder thus enhancing its maneuverability and providing ready visual and physical access

thereto for ease of placement and mounting of the occluder. Similarly, the heart valve anchor of the present invention solves a variety of problems associated with suture techniques including reduced valve size, pannus creep, and the in-growth of fibrosis which can cause valve failure. Furthermore, this procedure may be utilized without subjecting the patient to open chest surgery which reduces the incidence of infection to the patient in addition to the obvious reduction in the overall trauma experienced by the body.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view, partially broken away, of a prosthetic heart valve anchor device embodying the present invention;

FIG. 2 is a sectional view, in enlarged scale, taken the lines 2-2 of FIG. 1 and depicting a deployment tool engaged with such anchor device;

FIG. 3 is a sectional view, similar to FIG. 2, but showing rings in such anchor device shifted relative to one another;

FIG. 4 is a sectional view, in enlarged scale, showing the anchor driver device in a retracted position;

FIG. 5 is a broken perspective view of a deployment tool embodying the present invention;

5 FIG. 6 is perspective view, similar to FIG. 5, but showing the employment tool manipulated;

FIG. 7 is a longitudinal sectional view, in enlarged scale, taken along the line 7-7 of FIG. 5;

10 FIG. 8 is a perspective view showing the anchor device depicted in FIG. 1 engaged with the tool shown in FIG. 5;

FIG. 9 is a view similar to FIG. 8 but showing the anchor device being inserted in a native annulus;

FIG. 10 is a view similar to FIG. 9 but showing the retaining device as being deployed;

15 FIG. 11 is a perspective view of a second embodiment of the prosthetic valve anchor apparatus of the present invention;

FIG. 12 is a perspective view, partially in section, of the anchor device shown in FIG. 11 being inserted in an annulus;

20 FIG. 13 is a side view similar to FIG. 12 but showing the retaining device as being deployed;

FIG. 14 is a broken perspective view of the tool utilized to deploy the anchor device shown in FIGS. 12 and 13;

FIG. 15 is a partial broken vertical sectional view, in enlarged scale, taken along the line 15-15 of FIG. 14;

FIG. 16 is a perspective view of a third embodiment of the anchor device of the present invention;

FIG. 17 is a transverse sectional view of the anchor device shown in FIG. 16 being deployed by a deployment tool in a native annulus;

FIG. 18 is a sectional view showing the anchor device of FIGS. 16 and 17 retained in the annulus;

FIG. 19 is a side view of the tool utilized to deploy the anchor device shown in FIGS. 16 and 17;

FIG. 20 is a partial broken longitudinal sectional view, in enlarged scale, taken along line 20-20 of FIG. 19;

FIG. 21 is a perspective view, of a fourth embodiment of the prosthetic valve anchor apparatus of the present invention, showing the anchor device being inserted into a native annulus; and

FIG. 22 is a view similar to FIG. 21 but showing the retaining device as being deployed.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

The prosthetic heart valve anchor apparatus of the present invention includes, generally, outer and inner elongated concentric rings **42** and **44** with the top end of the inner ring being closed at its proximal end by a pair of hinged oblaters **46**. Referring to FIG. 2, the rings **42** and **44** are spaced radially apart to form therebetween an annulus **40** into which is received at the lower extremity a plurality of radially outwardly biased conformable retainer fingers **49**. Such fingers are mounted at their radially inner extremities to the bottom end of the inner ring **44** by means of anchor sleeves **48** and selectively retained in their retracted position by the bottom extremity **50** of the inner ring. With continued reference to FIG. 2, the inner and outer rings are formed with respective screw threads **43** and **45**. Laterally spaced apart legs **61** of a deployment tool, generally designated **60**, are engageable with the top end of the outer ring **42** and laterally spaced tines of a fork **63** are engageable with the top end of the inner ring **44**. Such legs and fork are rotated relative to one another to rotate such rings relative to one another to shift them longitudinally on their screw threads to shift the lower extremity **50** of such outer ring upwardly as such extremity **50** clears the free extremities of the retainer fingers **49** so they flex radially outwardly to the positions shown in FIG. 3 to project outwardly under the shelf of the annulus **65** (FIG. 10).

The rings **42** and **44** are constructed of a rigid or semi-rigid material such as titanium or plastic and then coated with a biocompatible substance such as pyrolytic carbon. In the preferred embodiment, the rings **42** and **44** are somewhat in the shape of inverted bells to flare longitudinally upwardly and radially outwardly as viewed in FIGS. 1 and 2. The outer ring **42** is formed in its distal extremity (FIG. 2) with the internal threads **45** to engage with external threads **43** formed on the wall of an actuator or coupler, generally designated **67**, mounted to a groove **77** in the exterior wall of the interior ring **44**. The upper extremity of the outer ring **42** is formed with a radially outwardly curved connector flange **87** formed with an upwardly opening blind drive bore **89**. The inner ring **44** flares outwardly to form a flare disposed above the proximal flare in the exterior ring **42** and in the path thereof to form a stop **86** (FIG. 3) to be abutted by the top side of the exterior ring flare to thus limit proximal travel of such exterior ring **42** relative to the interior ring **44**. The inner ring flare is formed on its top side with a circular bead **91** having a pair of diametrically oppositely disposed, upwardly opening drive bores **93** formed therein to be engaged by respective drive pins **123** formed at the end of the respective tines **63**. Such bead **91** is formed radially inwardly with a universal mounting socket **88** opening upwardly for receipt of a frame **90** mounting the occluders **46** (FIG. 3). It can be appreciated that the actuator **67** could take a variety of forms designed to translate movement, such as a pawl and ratchet mechanism actuable by reciprocation of such rings to progressively advance the relative rotation thereof.

It is understood by those skilled in the art that the shape of the rings of the anchor device may take a variety of forms not merely that of a bell. One could appreciate that the anchor may be formed in the shape of a pair of concentric rings which are deformable upon actuation. Additionally, the rings may even be formed in the shape of an hourglass with a flexible property for easy insertion at the annulus shelf. It can also be appreciated that the diameter and height of the anchor of the present invention cannot be limited. Since heart valve replacement procedures are conducted on infants, children and adults alike, there is a limitless variation of heart valve sizes which must be taken into consideration, thus the size of the apparatus cannot be limiting.

Referring to FIGS. 5 - 7, the deployment tool **60** includes a longitudinally elongated housing tube **103** bifurcated at its distal extremity to form radially outwardly projecting tubular legs **61** configured at their radial distal ends with drive pins **105** for selective engagement with the bores **89** of the anchor (FIG. 2). Pivotaly mounted at the distal extremities of such legs **61** adjacent such pins **105** are respective L-shaped pivotal claws **107** configured at their distal ends with respective laterally extending holding latches **109**. The tube **103** is formed intermediately with a pair of diametrically oppositely disposed longitudinal slots **111** (FIG. 7) about which are telescoped a sleeve **113** mounting a pair of diametrically opposed release finger rings **115**. Connected between the sleeve **113** and an intermediate location on the respective claws **107** are respective small push-pull wires **119** (FIG. 7) so that, when the rings **115** are

retracted upwardly, the claws **107** are drawn downwardly to their latching positions shown in FIGS. 2 and 6.

Longitudinally telescoped through the housing tube **103** is a push-pull wire **123** which mounts at its proximal end a knurled knob **125** and is formed on its distal extremity with the respective tines **63**, such tines being formed at their distal extremities with respective pegs **123** for receipt in the respective bores **93** (FIG. 2).

Mounted proximally on the housing tube **103** is a trigger fitting, generally designated **117**, for engagement with the surgeon's thumb when the fingers are received in the rings **115**. This trigger fitting permits stabilization and optimal hand comfort for the surgeon when using the deployment tool **60**.

The housing tube is constructed from a relatively rigid material such as plastic or titanium but could also be formed from stainless steel. The housing tube should be of sufficient length so as to allow easy and convenient access to the patient's heart from outside the chest cavity. In the preferred embodiment, the housing tube has a length of 30 cm for optimal access to the thorax but such length is not to be limiting since a shorter length may be appropriate for the pediatric procedure while a longer housing tube may be better suited for larger patients.

In operation, to perform a heart valve replacement surgery, access is gained to the heart by making a small incision at one of several locations such as the supersternal notch passing below or through the manubrium or sternum or via a mini-thoracotomy incision in the area between the first and second ribs enabling visualization of the aorta. A second parallel incision may be made for insertion of a trocar tube and placement therein of a monoscopic endoscope, coupled with a monitor, for optimal viewing of the valve site during the procedure. A hole is then made in the pericardium of the heart and the patient is placed on cardiopulmonary bypass using either a peripheral or central cannulation. At the surgeon's option, the aorta may then be cross-clamped and arrested using any of the usual techniques. A heart venting device can then be inserted and a small incision in a heart or great vessel above the annulus is made so the valve can be excised. Once this is accomplished the annulus is debrided as required. The anchor **39** will have been pre-fitted in its valve socket **88** formed with a universal mounter for use with any of the commercially available mechanical or tissue prosthetic valves (FIG. 2). The anchor **39**, with prosthetic valve in place, is then ready for attachment with the deployment tool **60**.

The anchor device **39** is then mounted to the distal extremity of the deployment tool **60** by inserting the pegs **127** of the tines **63** in the bores **93** and engaging the pegs **105** in the bores **89**. The surgeon may then grasp the actuating rings **115** and shift them proximally toward the trigger **117** to thus draw the respective claws **107** downwardly inwardly, as viewed in FIG. 7,

to thus draw the respective latches **109** under the flange **87** to latch such tool to the anchor device (FIG. 2). The latches **109** function as a stabilizing device to secure the tool **60** attached to the anchoring device **39** and prosthetic valve may then be inserted through the thoracic incision and advanced to position such anchor device in the optimal location along the heart valve annulus and nested at the shelf **65**, as shown in FIG. 9. Optimal placement of the device **39** will locate the radially out-turned flange **87** such that it will nest on top of the annular shelf **65** acting as a stop ring to prevent further insertion. With the anchor device **39** so positioned, the actuating knob **125** may rotate in one direction to screw the outer ring **42** upwardly relative to the inner ring **44** until it reaches the position shown in FIG. 3 engaging the outer tube flare with the inner flare stops **86**. At this point, the retainer extremity **50** at the bottom of the outer ring **42** will clear the resilient retainer fingers **49** thus releasing the free ends of such fingers to spring radially outwardly to the respective position shown in FIG. 10 and engaging under the shelf of the annulus **65**. This will then serve to secure the anchor device **39** firmly and atraumatically in position in such annulus.

The surgeon can then grasp the actuating rings **115** (FIG. 5) and pull upwardly thereby driving the sleeve **113** distally to thus shift the push-pull wires **119** driving the claws **107** upwards, as shown in FIG. 7, to release the respective latches **109** from under the ledge **87** (FIG. 2). This then will free the tool **60** to be withdrawn. The aortotomy may then be closed using

traditional suturing technique or vascular staples. The heart can then be de-aired and the crossclamp removed. If an endoscope is utilized for viewing purposes, removal of the corresponding trocar tubes and endoscope may be effected. The patient is now ready to be removed from cardiopulmonary bypass. Once the patient is off bypass, the exterior wound may be closed and sutured using traditional technique.

It will be appreciated that the retainer fingers **49** are constructed from a flexible yet resilient metal or plastic material which is capable of being collapsed when withdrawn into the anchor before deployment and then released to its opened position upon deployment of the anchor device. Such a material may possess a spring-like quality or other sense memory so as to provide an added tension quality for enhanced security and tension against the annulus shelf when deployed. In the preferred embodiment, when fully deployed, the retainer fingers include a bent portion having a curved outer radius **51**. This curved portion **51** enhances the surface area of the retainer fingers **49** in contact with the annulus shelf **65**, thereby augmenting the gripping capabilities of the retainers. It can be appreciated that the shape and structure of the retainers can vary widely. The retainers may in fact take a variety of forms including that of a resilient retractable spring-like finger **317** (FIG. 22) which projects radially outwardly and upwardly to cup under the shelf of the annulus and thereby secure the anchor in place. Alternatively, the retainer fingers need not project from the distal end of the anchor. In one proposal, the retainer

fingers may project and retract from axial windows which are formed about the periphery of the anchor device.

It will be appreciated that, in the event the prosthetic valve device mounted by the anchor device of the present invention should fail the heart valve may be reaccessed as set forth above and the valve occluder 46 removed leaving the anchor ring in place. Such anchor may then be cleaned up and the occluder replaced. In addition, should it be necessary to remove the anchor, a tool like that described hereinabove may be used to withdraw the retainer elements 49 radially outwardly to clear the annulus for removal. The deployment tool 60 may then be actuated by grasping the knob 125 drawing it proximally to retract the tines 63. Concurrently, the rings 115 may be grasped and driven distally to drive the claws 107 counterclockwise as viewed in FIG. 7 to open such claws. The tool may be advanced to engage the prongs 105 with the flange 87. The housing tube 103 may then be rotated while holding such prongs 105 engaged against such flange 87 to thus register such prongs with the bores 89. It will be appreciated that in some embodiments of the present invention an upwardly opening groove is formed about the flange 87 on the diameter including the bores 89 to guide such prongs 105 as they are orbited about to locate such bores. Once such prongs 105 are engaged, the latch rings 115 may be advanced distally to rotate the claws 107 to latch under such flange 87. The knob 125 may then be grasped and advanced distally while holding the housing tube 103 stationary. Once the tine

prongs **123** engage the inner ring flange **91**, the knob **125** may be rotated until such prongs **123** engage the bores **93**. The knob **125** may then be advanced to engage such prongs firmly in the bores **93** and the tool components held steadily as the knob is rotated to advance the screw thread actuator **67** thereby moving the outer ring **42** downwardly so as to advance such retainers radially inwardly to engage the bottom end of the retainer skirt **50** medially with the free ends thereof to clear the underside of the annulus (FIG. 4) while holding the latch rings proximally to hold the latches **109** secure on the flange and the surgeon may grasp the housing tube **103** and draw it proximally to remove the anchor.

Referring to FIGS. 11 through 13, a second embodiment of the anchor apparatus of the present invention, shown without the prosthetic valve in place, includes, generally, a ring forming a band **131** having upper and lower ring elements **133** and **135**. Interposed between the upper and lower ring elements **133** and **135** is an actuating ring, generally designated **134**, configured with diamond shaped fold-inducing openings **137** spaced peripherally thereabout and configured and arranged to form therebetween axial panels **138** having their respective narrowest annular dimension on a circumferential line positioned to be, when the band is compressed axially splayed radially outwardly under the annulus shelf (FIG. 13) to cooperate in defining a retainer ring, generally designated **147**. The ring may be constructed of a stressed metal covered with a biocompatible substance, or a semi-rigid plastic capable of a spring memory so that upon

deployment, the anchor device will retain the axially shifted configuration without additional support.

The ring is so configured and so shaped that, when axially compressive forces are applied thereto, it will assume the modified hourglass shape shown in FIG. 13. The actuating ring **134** may include a variety of constructions to achieve the necessary preferential bending. In one instance, the materials may be pre-stressed to achieve the desired form; in another example, the actuating ring may comprise a weakened area which will partially collapse upon axial column loading while operating to drive the retainer ring section **147** radially outwardly under the annulus.

Referring to FIGS. 14 and 15, the second embodiment of the deployment tool, generally designated **160**, includes an elongated housing tube **173** formed on its distal end with radially outwardly and distally projecting legs **161** formed at their radial distal ends with pusher forks **169** formed with inverted U-shaped pairs of tines **168** for engagement with the upper ring element **133** (FIG. 12). The deployment tool **160** is formed on the distal end of the housing tube **173** with a concentric, downwardly opening hollow retractor cone **165** terminating in a retractor edge **166**.

The housing tube **173** houses an interior actuator wire **181** capable of longitudinally telescopic axial movement within the housing **173**. The actuator wire **181** is formed distally with a plurality of external screw threads **177** screwably engaged with oppositely placed internal screw threads **175** formed in the distal end of the housing tube **173**. Formed at the distal extremity of the actuator tube **181** are radially outwardly and distally projecting resilient legs **163** formed at their distal ends with respective radially out-turned L-shaped engagement hooks **167**. Such legs **163** are formed with an inherent bias to push such hooks radially outwardly into a circular pattern having a diameter slightly larger than the diameter of the distal ring section **135** (FIG. 13). The engagement hooks **167** are configured to securely grasp and engage the distal edge of the ring **135**. The proximal extremity of the tubular housing **171** is formed with an enlarged-in-diameter knurled tubular handle **171** having abutted against the proximal end thereof the distal shoulder of an enlarged-in-diameter cylindrical handle formed at the proximal end of the wire **181**.

In operation, the deployment tool **160** may be attached to the anchor **131** device by advancing the wire **181** to shift the legs **163** distally. The legs **163** may be pressed radially inward by hand to allow the ring anchor **133** to be fitted thereover to be moved proximally of the hooks **167**. Such legs may be then released to engage such hooks with the distal edge of the ring section **135** (FIG. 12). Concurrently, the forks **168** may be engaged over the proximal edge of

the ring section **133**. Access will be gained to the anatomy as described above. The tool carrying such anchor is then inserted into the patient using the surgical technique described hereinabove to be located at the annulus shelf site. When the anchor has been placed in the desired location, the activating handle **172** may be grasped and rotated while holding the housing handle **171** to rotate the mating threads **177** and draw the wire **181** proximally to retract upwardly to draw the engaging hooks **167** proximally relative to the forks **169** to apply column loading to the ring **131**. The application of such compressive force will cause the central actuator ring **134** to assume its preferential orientation driving the axially central parts of the panels **138** radially outwardly to form the retainer ring **147** (FIG. 13). Such panels **138** will thus exceed their tensile strength thus becoming overstressed to cause the anchor **131** to be retained in the hourglass shape of FIG. 13 with the retainer ring **147** pushed radially outwardly under the shelf of the annulus **65**. At the maximum position of radial projection of the ring **131**, the legs **163** will have been drawn proximally to the point at which they abut against the bottom edge portion **166** of the retractor cone **165**. Thereafter, the surgeon can continue to rotate the upper knob **172** to draw the wire **181** further proximally to draw the proximal roots of the collapsible legs **163** further proximally and into such cone so as to flex such legs radially inwardly and disengage the hooks **167** from the bottom portion of the ring **135**. The deployment tool may then be removed from the patient. The patient may then be taken off bypass, have the surgical openings closed and the procedure completed.

Should the occasion arise where the prosthetic valve shown in FIG. 11 is to be removed or replaced, a tool like that described above may be employed to retract the anchor ring **131** and remove the device from the annulus shelf. Such a tool will employ legs and tines like those shown except with clamps on the distal extremities thereof for grasping the respective top and bottom of the ring **131**. The heart valve must first be reaccessed using the surgical techniques previously described herein. Thereafter the deployment tool **160** may be used by first retracting the legs **163** to their fully retracted position within the cone **165** so that the tool may be inserted into the patient and placed such that the clamps in the respective forks **169** and tines **168** are in engagement with the respective top and bottom ends of the ring **131**. The upper knob **172** may then be rotated to actuate the screw threads so as to drive the wire **181** distally to apply tensile forces to the ring **131** causing it to straighten to the position shown in FIG. 11 with the retainer ring drawn radially inwardly to clear the annulus **65** as such tool is drawn proximally to remove the ring **131**.

The third embodiment of the prosthetic valve anchoring device of the present invention shown in FIGS. 16 - 18 without the prosthetic valve in place, includes a band, generally designated **201**, somewhat similar to that shown in FIG. 11. The band **201** is formed with proximal and distal ring elements **203** and **205**, respectively, and an actuator ring element **204** interposed between the proximal and distal elements. The distal ring element **205** is

constructed with a retainer ring element, generally designated **200**, having diamond shaped cut outs **202** spaced annularly apart to form said bands **206** which, when axial forces are applied, will splay radially outwardly to assume a diameter larger than that of the annulus to form an enlarged-in-diameter retainer.

5 Mounted about the interior of the proximal band element **203** are a plurality of rectangular latch brackets **207** configured with longitudinal passages. Corresponding elongated resilient latches, generally designated **211**, are cantileverly mounted on the distal band element **205** and are bifurcated to form tines **209** configured on their respective free ends with modified arrowhead shaped catch teeth **210**. Thus, when the axially compressive forces are applied to the anchor band **201** to axially compress such band, such latches will be driven toward the respective passages in the brackets **207** to engage the catch teeth **210** of the respective tines **209** with the circumferentially opposite ends of such bracket to be flexed therein laterally inwardly toward one another until they clear the respective brackets **207**. The tines will then snap laterally outwardly to cause the catch teeth **210** to latch in the position shown in FIG. 18 to lock against release.

15 Referring to FIGS. 19 and 20, the third embodiment of the deployment tool, generally designated **260**, includes an elongated tubular housing **271** formed on its proximal end with a hand grasp knob **273** reduced in diameter centrally to form a waist. Such housing

terminates at its distal end in a retractor edge **276** (FIG. 20) which may be conically shaped.

Telescoped through such housing **271** is an intermediate actuator tube **275** having mounted at its proximal end a pair of trigger loops **215** (FIG. 19). These trigger loops **215** also comfortably

stabilize the surgeon's hands when using the deployment tool in a manner similar to the trigger

fitting shown in FIGS. 5 and 6. Formed on the distal end of the actuator tube **275** are radially

outwardly distally projecting resilient legs **261** configured at their radial distal ends with

respective L-shaped proximally facing hooks **267**. Referring to FIG. 20, such legs are so

positioned that, upon retraction of the actuator tube **275**, they will engage the retractor edge **276**

to be drawn radially inwardly. The L-shaped hooks **267** are configured to engage under the

distal edge of the band **205** for deployment of the anchor **201**. Formed at the distal end of the

actuating wire **281** are radially outwardly and distally projecting legs **263** configured at their

distal ends with pusher forks **269** having inverted U-shaped tines **268** for secure nesting with the

proximal edge of proximal ring element **203** (FIG. 16). The surgeon may then pull the ring **217**

proximally to retract the actuating wire **281** proximally causing the hooks **267** to move

proximally thereby exerting column load on the band thereby compressing the band **201** axially

as described above causing the latch forks **211** to be driven into the respective passages of latch

brackets **207** thereby securing the anchor **201** in such deployed position, as shown in FIG. 18.

As the anchor band **201** approaches full deployment, the anchor ring **201** will be sufficiently crushed axially so the tube **275** will be drawn sufficiently far proximally in the tube **275** to cause the roots of the legs **261** to engage the retractor edge **276** (FIG. 20) to drive such legs radially inwardly to disengage the respective hooks from the distal edge of the ring element **205** (FIG. 18). The tool may then be removed.

The embodiment of the prosthetic anchor device **301** shown in FIGS. 21 and 22 is similar to the construction shown in FIG. 1. Here, generally, the anchor device **301** includes a bell shaped ring **305** having annularly spaced apart inner and outer walls to be configured with a downwardly opening annulus which receives axially therein a plurality of vertically projecting formed retainer springs **317** which may be configured on their lower extremities with light coil springs. Such retainer springs **317** are deployed vertically downwardly to take their inherent set projecting radially outwardly to engage under the shelf of the annulus **65** below the minor diameter thereof.

Any one of a number of different deployment actuation devices may be utilized to deploy such retainer rings **317**. One such mechanism may be like that shown in FIG. 21 where formed tubular elements **313** are configured in alignment with such springs **317** and are opened at the top end for longitudinal receipt of pusher tines which engage therewith and are advanced

downwardly axially to push against the top ends of the respective springs **317**. In this configuration, it will be appreciated that the mounting ring **309** of the prosthetic is itself formed with bores **315** configured to be aligned with the bores **313**.

In another modification, the actuating mechanism is in the form of inner and outer bell shaped rings spaced apart to form an annulus and rotatable relative to one another about their central axes. In that configuration, the top extremities of the respective retainer springs **317** are anchored to one of the rings and passes medially over a pair of close spaced, radially projecting pegs and downwardly through vertical tubes defining passages so that, as one ring is rotated relative to the other, such springs **317** are either advanced downwardly in the respective tubes for deployment or are retracted upwardly in the respective tubes for retraction. In either of these configurations, relative rotation of the two rings may be established by a deployment tool similar to the device shown in FIGS. 5 and 6. In a further modification, such retainer springs are telescopically received in open ended stub tubes **311** mounted around the interior of the ring **305** and are advanced outwardly therethrough by relative rotation of a complementally shaped inner actuation ring (not shown) to which the top ends thereof are tethered for advancement and retraction as such inner end is rotated in opposite directions.

It will be appreciated that the method of placement and retaining of the heart valve anchor utilizing the present invention will facilitate stabilization of the anchor at the

annulus during the delicate placement portion of the surgery to achieve reduced trauma to the patient, as well as offering secure retaining of the device after deployment using less invasive technique. Furthermore, both the anchor device and deployment tool are manufactured using a minimal number of moving parts thereby eliminating altogether or reducing moving parts which may break or become misplaced prior to or during the surgery. Additionally, in some of the embodiments, the anchor device can be formed as a single unit thereby permitting the greatest strength possible in the overall apparatus.

From the foregoing, it will be appreciated that the anchor device of the present invention is economical to manufacture and can be inserted using minimally invasive surgical procedures in a relatively rapid manner without the usual tedious and time consuming tasks typically associated with suturing. The device provides for secure and positive anchoring in the native annulus and possesses the characteristics that the procedure might be reversed to remove the anchor device for replacement of the occludators.

Various modifications and changes may be made with regard to the foregoing detailed description without departing from the spirit of the invention.

WHAT IS CLAIMED IS:

1. A method for implanting a heart valve in a patients heart annulus

including:

selecting an anchor device for receipt through said annulus including spaced apart ring elements shiftable relative to one another from recessed to deployed positions and a retainer retained between said rings operable upon said rings being shifted from a retainer recessed position to a retainer deployed position projecting radially outwardly;

accessing an artery of said patient and inserting said anchor device therethrough to position it in said annulus; and

shifting said rings relative to one another to said deployed position to shift said retainer to said retainer deployed position.

2. The method for implanting a heart valve anchor as set forth in claim 1,

wherein:

said step of selecting said anchor device includes selecting said anchor device to include a radially outwardly projecting stop ring on the proximal end thereof; and

said steps of inserting said device includes inserting it sufficiently far to position said stop ring on the proximal side of said annulus.

3. The method for implanting a heart valve anchor as set forth in claim 1, that includes the steps of:

after shifting said retainers to said deployed positions, shifting said rings to said recessed position to shift said retainers from said retainer deployed position to said retainer recessed position.

4. The method for implanting a heart valve anchor as set forth in claim 1, that includes: imbedding said retainers in said annulus.

5. The method for implanting a heart valve anchor as set forth in claim 1, wherein: said step of shifting said rings includes rotating them relative to one another.

6. The method for implanting a heart valve anchor as set forth in claim 1, wherein: said step of shifting said rings includes shifting them axially relative to one another.

7. The method for implanting a heart valve anchor as set forth in claim 1,

wherein:

said step of inserting said device includes selecting an elongated introduction tool having a semi-rigid tubular tool housing and an elongated deployment rod projecting therethrough and coupling the distal end of said tool housing with one of said rings and the distal extremity of the other ring with the other of said rings.

8. An implantable anchor device for anchoring in an annulus and comprising:

first and second ring elements for receipt in said annulus, said rings spaced apart with one shiftable from a retracted to a deployed position; and

a retainer device interposed between said rings and operable upon said one ring being shifted to said deployed position to project radially outwardly to engage under the shelf of said annulus.

9. An anchor device as set forth in claim 8, wherein:

said first ring element includes a stop in said predetermined path to limit movement of said second ring element.

10. An anchor device as set forth in claim 8, wherein:

a coupler is coupled between said rings for coupling said rings together for shifting relative to one another from a retracted position to said deployed position

11. An anchor device as set forth in claim 8, wherein:

said ring elements are shiftable axially relative to one another; and

said retainer includes a plurality of flexible axial strips configured to, when said one ring element is in said retracted position, assume respective axially projecting positions and to, when said one ring element is shifted to said deployed position, flex radially outwardly.

12. An anchor device as set forth in claim 11, wherein:

said device includes said strips being configured to, when said one ring element is shifted to said deployed position, flex radially outwardly.

13. An anchor device as set forth in claim 8, wherein:

said coupler includes screw threads.

14. An anchor device as set forth in claim 8, wherein:

said ring elements are concentric with one another.

15. An anchor device as set forth in claim 8, wherein:

said ring elements are flared to project radially outwardly at their proximal extremities.

16. An anchor device as set forth in claim 8 that includes:

a driver mounted on one of said rings and operative upon shifting of said one ring to said deployed position to drive said retainer to its deployed position.

17. An anchor device as set forth in claim 8 that includes:

an elongated band configured to form said first and second ring elements on the proximal and distal extremities thereof, said distal extremity being configured to, upon said proximal and distal extremities being shifted axially towards one another, project radially outwardly to form said retainer.

18. An anchor device as set forth in claim 17 wherein:

said band is constructed of material having a memory.

19. An anchor device as set forth in claim 17 wherein:

said band is constructed of a resilient material and is configured so that, upon said proximal and distal extremities being drawn toward one another, will take a set with said distal extremity disposed radially outwardly to act as said retainer.

20. An anchor device as set forth in claim 17 that includes:

a first latch element mounted on said proximal extremity and a second latch element mounted on such distal extremity, said latch elements being configured to, upon said proximal and distal ring elements being drawn a predetermined distance toward one another, extend said distal extremity outwardly to said retaining position to latch together.

21. An anchor device as set forth in claim 20 wherein:

said first latch element includes a passage formed therein; and

said second latch element includes an axially elongated tab cantileverally mounted on said distal extremity and projecting toward said latch and further constructed of spring material and having at least one distal tooth configured to flex laterally as it engages said latch and to, upon said first and second ring elements being shifted to said deployed position, engage behind said latch.

22. An anchor device as set forth in claim 17 wherein:

said band includes a weakening strip interposed therebetween for enhancing bending thereof.

23. An anchoring device as set forth in claim 8 wherein:

said ring elements are in the form of elongated concentric rings rotatable relative to one another to deploy said retainer;

said one ring element includes an inner ring and an outer ring, said outer ring including a plurality of retainer windows; and

said retainer includes a plurality of resilient fingers cantileverally mounted on said inner ring and registered on their free extremities with said windows, said retainer fingers being configured such that rotation in one direction of said inner ring relative to said outer ring, the distal extremities of said retainer fingers will project through said windows and be directed radially outwardly to a retaining position.

24. An anchoring device as set forth in claim 23 wherein:

said outer ring is formed with said windows positioned relative to said retainer fingers such that, upon continued rotation of said outer ring relative to said inner ring beyond said deployed position, said retainer fingers will be retracted radially inwardly from said retained position.

25. A heart valve anchor device for anchoring a valve in a heart annulus of a patient comprising:

an elongated ring device including a ring housing configured on its proximal extremity with a laterally outwardly flared stop ring to nest against the proximal side of said annulus; and

a plurality of movable retainers carried by said ring device to project laterally outwardly to respective retaining positions from the distal extremity thereof.

26. A heart valve anchor device as set forth in claim 25, wherein:
said retainers are resilient.

27. A heart valve anchor device as set forth in claim 25, that further includes:
a retractor for retracting said retainers laterally inwardly from said retaining positions.

28. A heart valve deployment tool for deploying a prosthetic heart valve having first and second anchor ring elements shiftable relative to one another for deploying a retainer to anchor a heart annulus and comprising:

an elongated housing tube including on its distal extremity a plurality of
5 outwardly diverging legs configured on their respective distal extremities with first engaging
elements for engaging said first ring element;

an actuator received in said tube and formed on its distal extremity with outwardly
diverging tines configured on their respective distal extremities with second engaging elements
for engaging said second ring element; and

10 a handle mounted on the proximal extremity of said actuator to be grasped to shift
said actuator relative to said housing tube to shift said tines relative to said legs to shift said
second ring element relative to said first ring element to deploy said retainer.

29. A deployment tool as set forth in claim 28 that includes:

latches mounted on the distal extremities of said legs and shiftable between a
latching position engaging said second ring element and a retracted position;

a latch release handle mounted on the proximal end of said housing tube and
5 shiftable relative thereto; and

a wire connected between said latch handle and said latches.

30. A deployment tool as set forth in claim 29 wherein:

said housing tube includes at least one longitudinal slot adjacent said latch handle;

and

said wire device projects through said slot.

31. A deployment tool as set forth in claim 29 wherein:

said latches are in the form of claws pivotally mounted to said legs.

32. A deployment tool as set forth in claim 28 wherein:

said actuator is rotatable relative to said tube for rotating said tines relative to said

leg.

33. A deployment tool as set forth in claim 28 wherein:

said actuator is shiftable longitudinally relative to said tube for shifting said tines

longitudinally relative to said legs.

34. A deployment tool as set forth in claim 28 for use with a prosthetic heart

valve having an elongated anchor band having proximal and distal ends shiftable relative to one

another for deployment of said retainer and wherein:

said legs include hooks for projecting longitudinally through said band to hook on

the distal extremity thereof; and

said tines include pushers on the distal end thereof for engaging the proximal

extremity of said band.

35. A heart valve deployment tool as set forth in claim 28 wherein:

said tines are flexible and slope outwardly and distally and said tool includes a retractor cone mounted on the distal extremity of said tube and configured to, upon retraction of said tines into said cone, engage said tines and flex them radially inwardly; and

said housing tube is configured so said actuator is longitudinally telescoped therein to retract said tines into said cone.

36. An anchor for receiving a prosthetic heart valve to anchor it to an annulus and comprising:

a circular ring housing;

a plurality of retainers movably carried from said housing and moveable from a retracted position to a deployed position to project on their respective one extremities radially outwardly therefrom; and

an actuator mounted from said housing and engaged with said retainers, said actuator being moveable relative to said housing ring to shift said retainers from said retracted to said deployed positions.

37. An anchor for receiving a prosthetic heart valve as set forth in claim 36

wherein:

said retainers are resilient.

38. An anchor for receiving a prosthetic heart valve as set forth in claim 37

wherein:

said retainers are in the form of elongated springs mounted on their respective one ends to said housing and configured with respective free extremities forming the respective said one extremities.

39. An anchor for receiving a prosthetic heart valve as set forth in claim 36

wherein:

said retainers are generally U-shaped.

40. An anchor for receiving a prosthetic heart valve as set forth in claim 36

wherein:

said actuator includes an actuator ring coupled to said housing ring.

41. An anchor for receiving a prosthetic heart valve as set forth in claim 36

that includes:

a coupler coupling said actuator to said housing for guided travel of said actuator through a predetermined path and wherein:

said housing includes a stop disposed in said path to limit travel of said actuator.

42. A method of implanting a heart occluder anchor in an annulus including:

selecting a heart valve anchor for receipt in said annulus and of the type including extendable retainers for selectively engaging said annulus and an occluder connector for connection with said occluder; and

selecting an intraluminal implant tool, coupling it with said ring, advancing said anchor ring intralumenally to said annulus and deploying said retainers to engage said annulus.

43. The method as set forth in claim 42 that includes:

selecting an occluder including a connector for removable connection with said first mentioned connector, introducing it intralumenally to said annulus and connecting it to said first mentioned connector.

44. The method as set forth in claim 42 that includes:

selecting said anchor ring of the type having said connector in the form of a bayonet style connector.

45. The method as set forth in claim 42 that includes:

selecting said anchor ring of the type having said connector in the form of a rotary engageable and disengageable connector.

46. The method as set forth in claim 43 that includes:

reaccessing said annulus, removing said occluder, introducing a second occluder and connecting it to said first mentioned connector.

47. A heart valve anchor device for implant in a heart annulus including:

an anchor ring for receipt in said annulus;

a retainer device on said ring for selective extension into holding contact with the wall of said annulus;

an actuator on said ring for extending said retainer device; and

an occluder connector device on said ring for removably mounting an occluder.

48. The heart valve anchor device as forth in claim 47, wherein:

said occluder mounting device includes a rotary connector.

49. The heart valve anchor device as set forth in claim 47, wherein:

said occluder mounting device includes a bayonet thread.

ABSTRACT

A method of implanting a universal heart valve prosthetic anchor device for receipt of a mating occluder. The anchor device includes a pair of rings axially shiftable from a retracted to a deployed position. The anchor device further formed with a plurality of flexible retaining elements received within the anchor rings and which are capable of laterally downwardly outward movement upon deployment of the rings. The deployment tool includes an elongated tubular housing mounted at its distal end with radially outwardly diverging tines for reversible engagement with the anchoring rings. A wire is telescoped through the tines for actuation of the fork thereby causing deployment of the anchoring rings. Once placed at the desired location within the heart muscle, the deployment tool is actuated causing the anchor device to shift axially thereby causing the retainers to deploy outwardly and upwardly to secure the valve anchor in place at the heart valve annulus shelf.

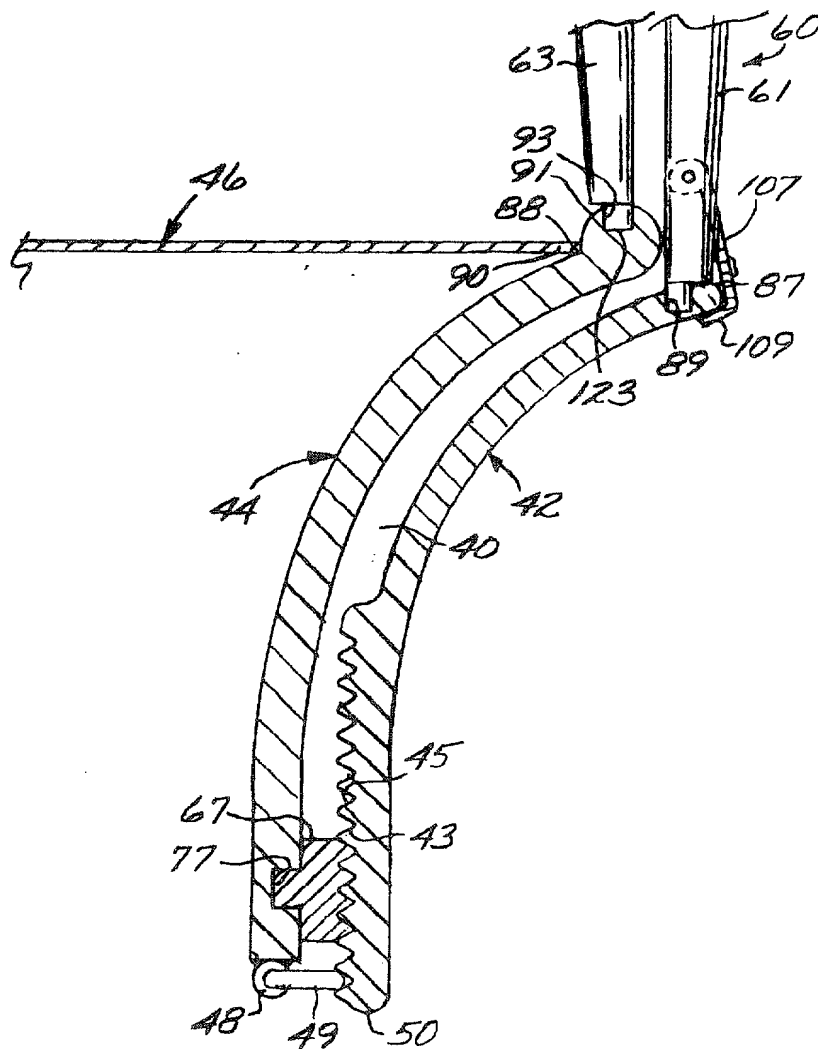
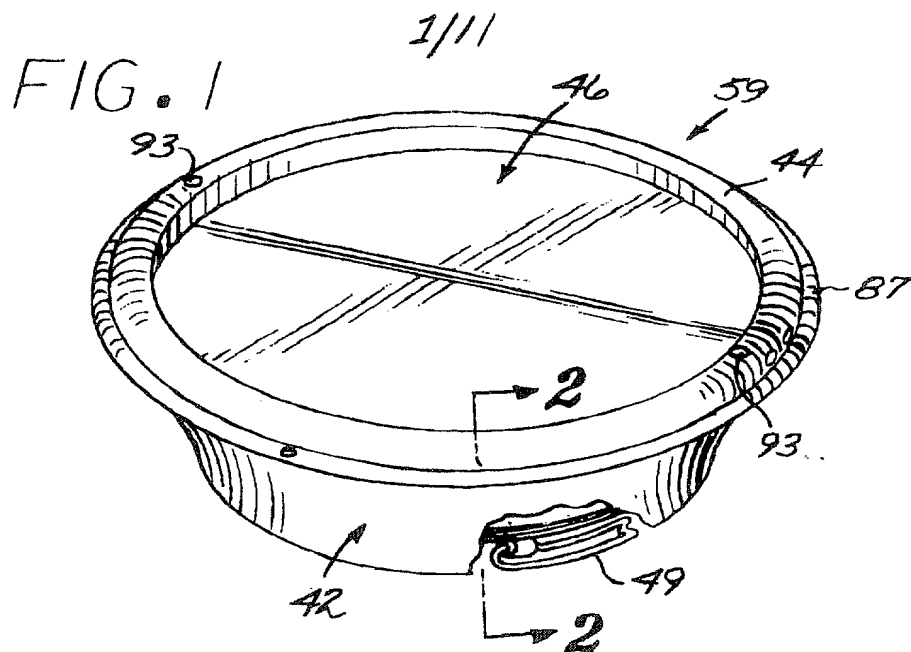
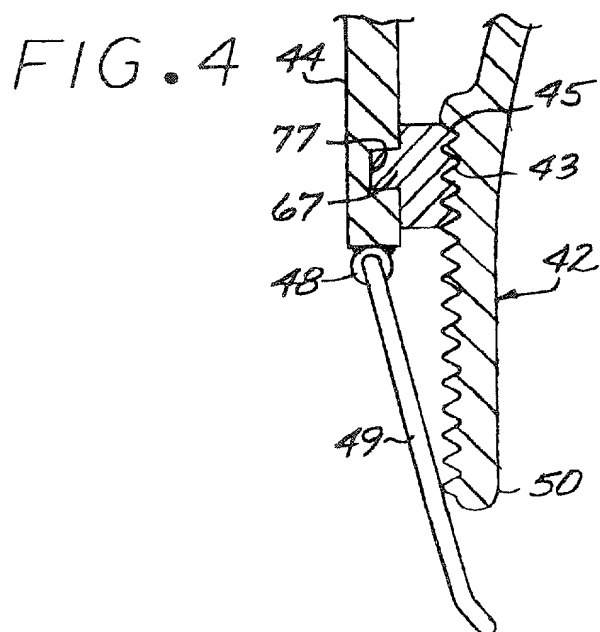
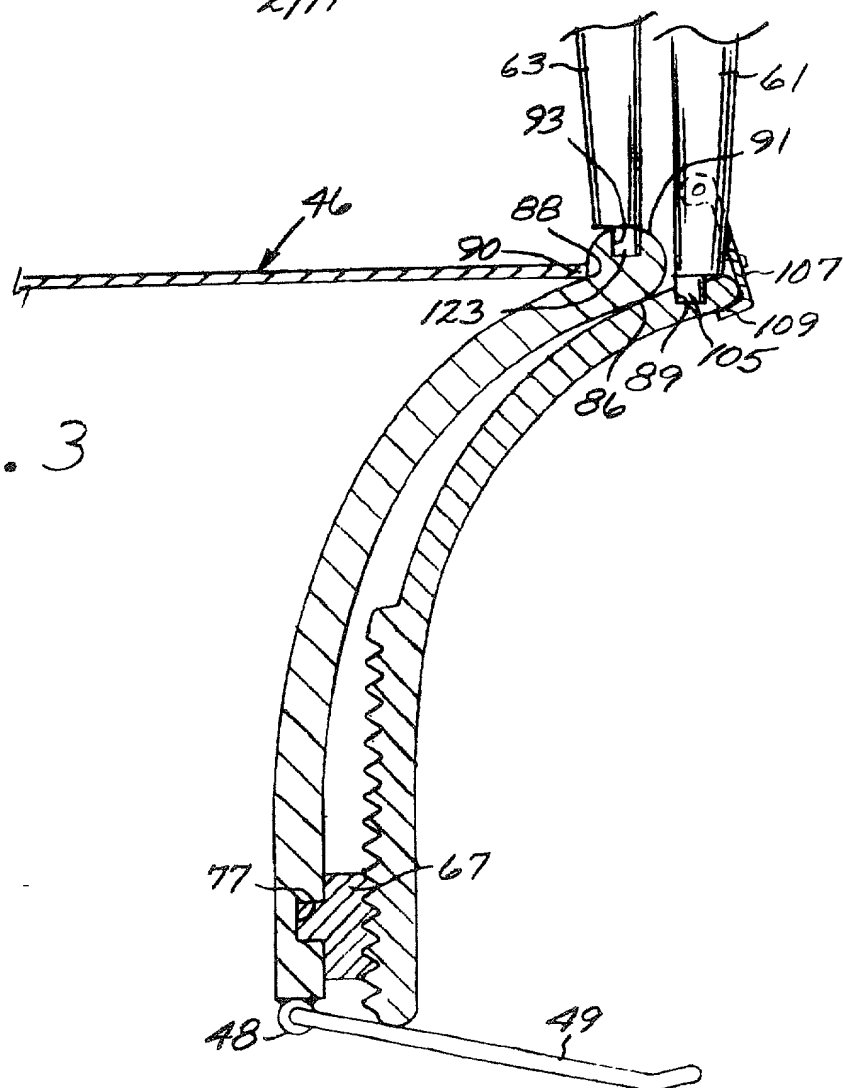
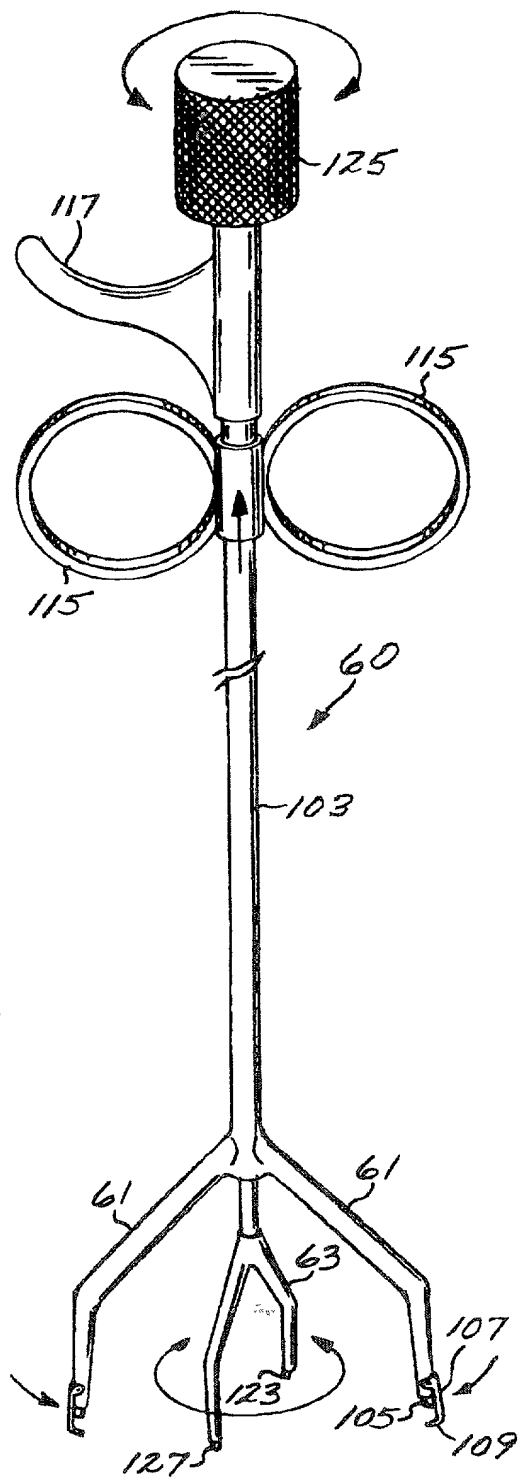
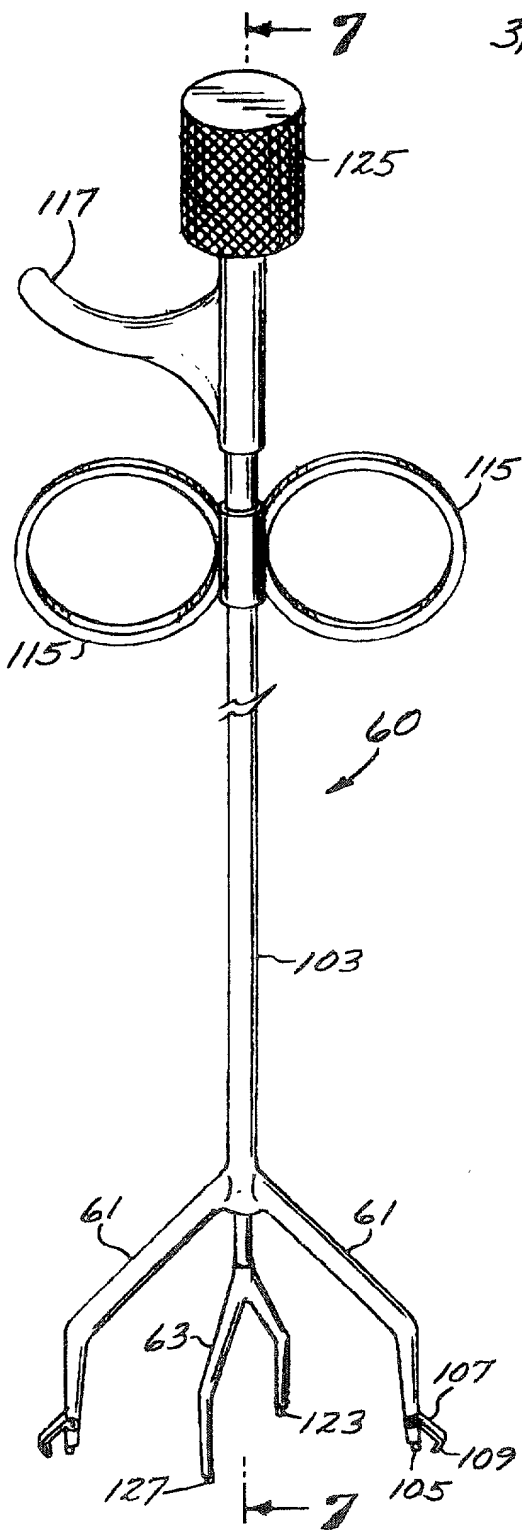


FIG. 2



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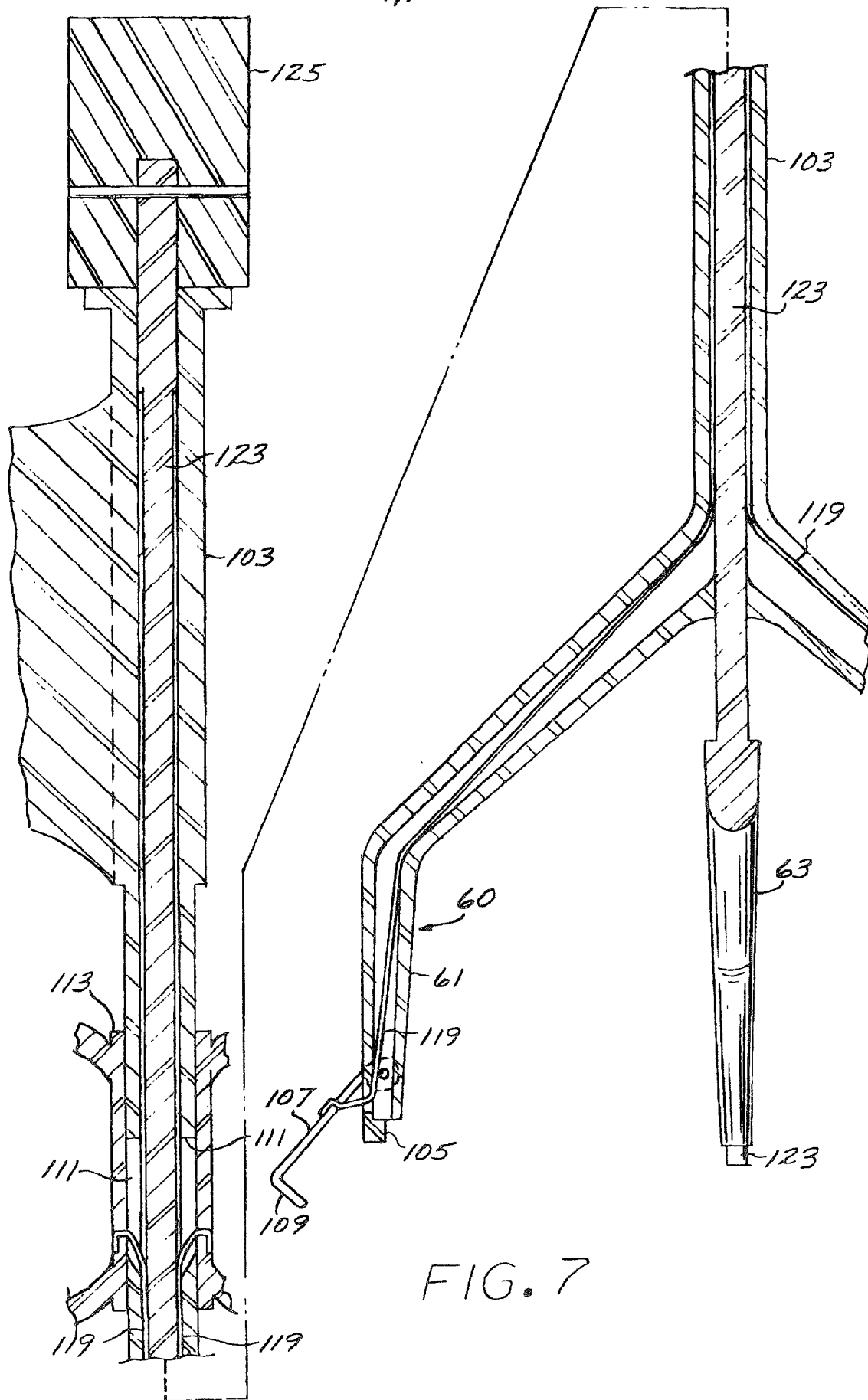
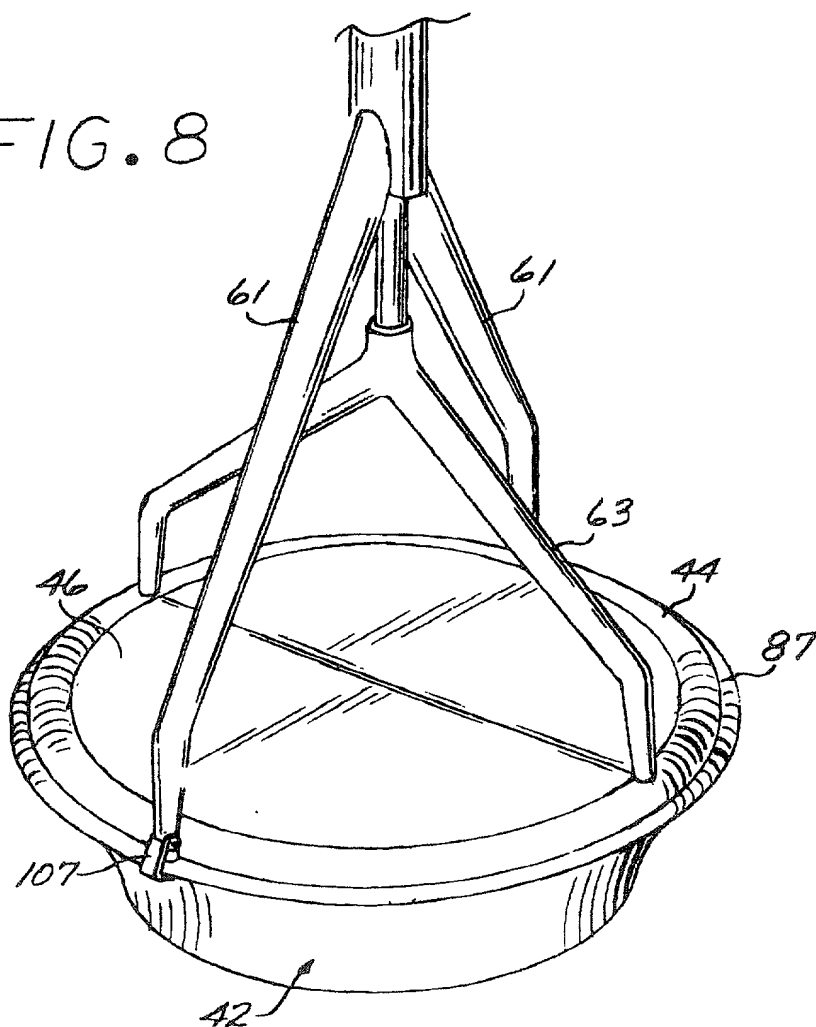


FIG. 7

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FIG. 8



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FIG. 9

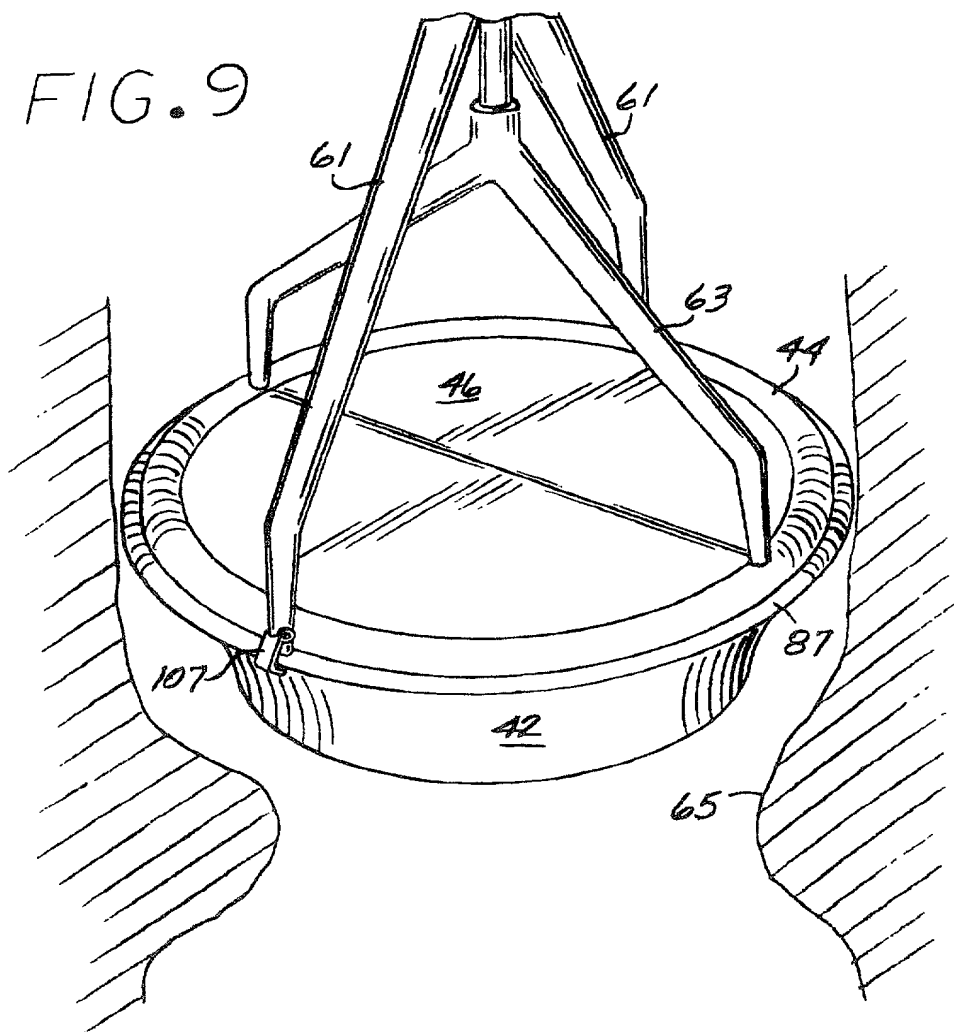
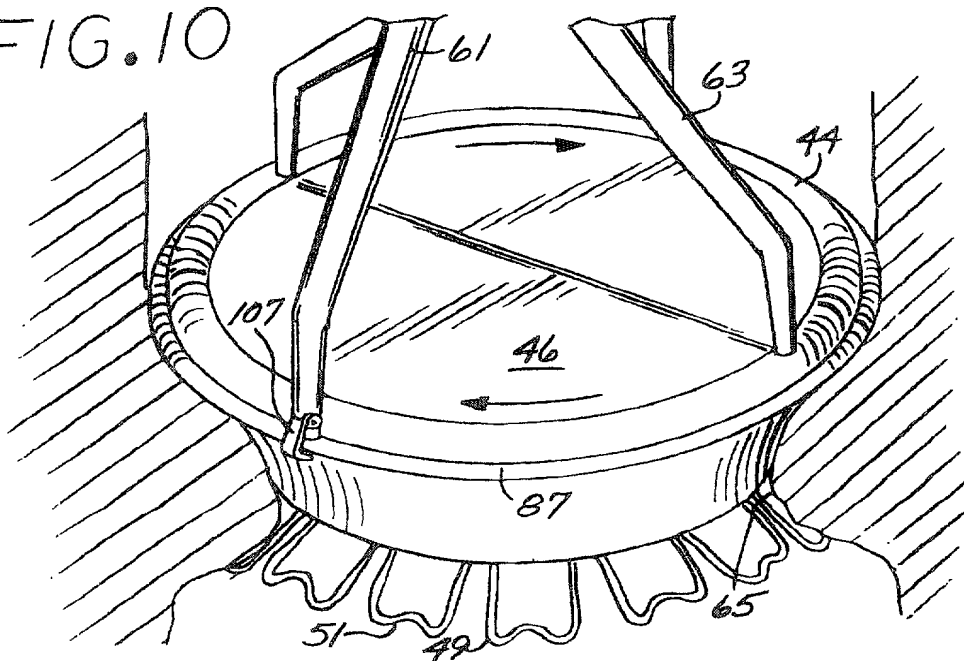


FIG. 10



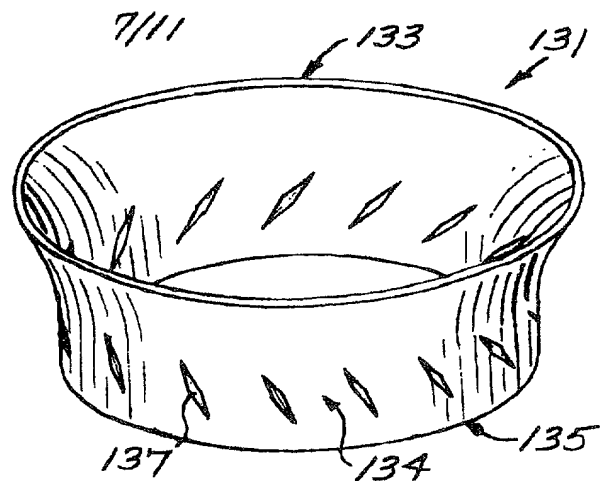


FIG. 11

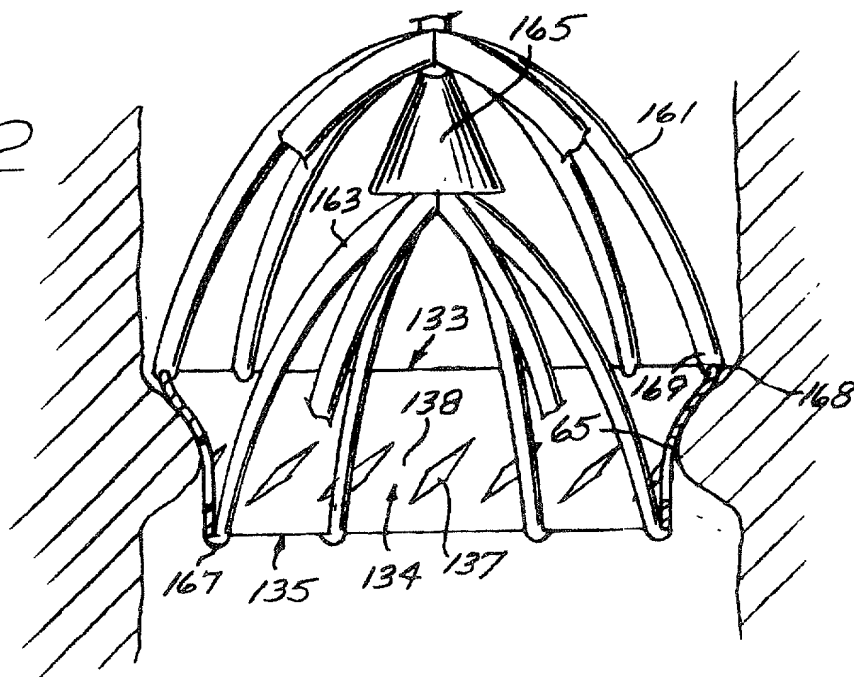


FIG. 12

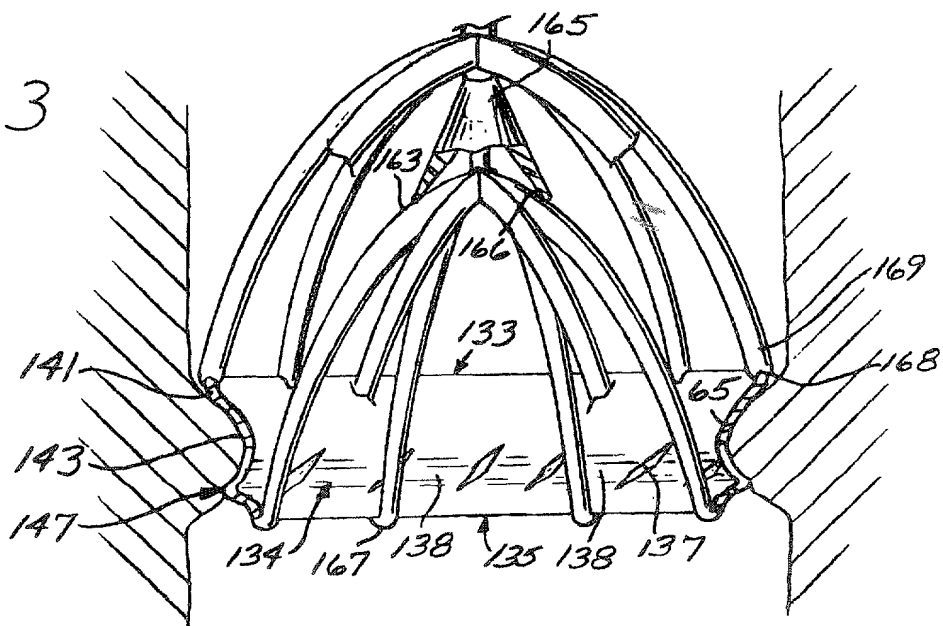


FIG. 13

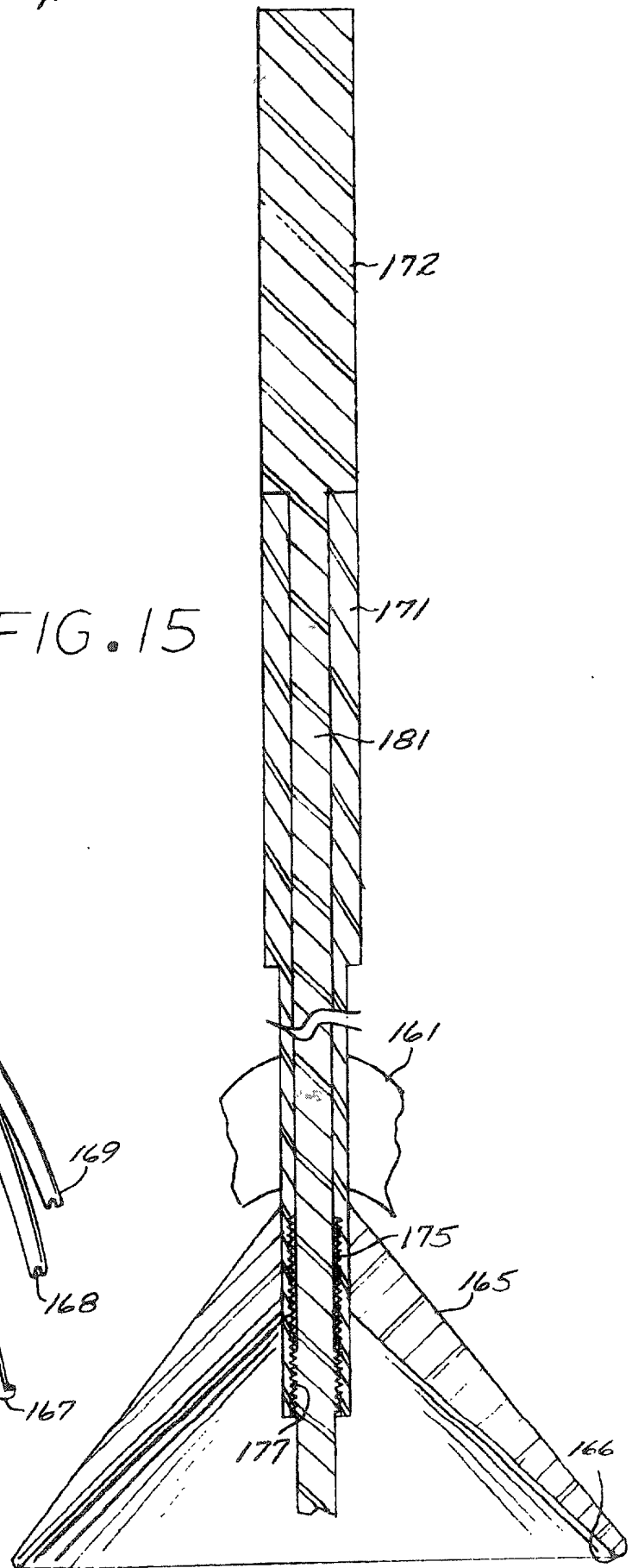
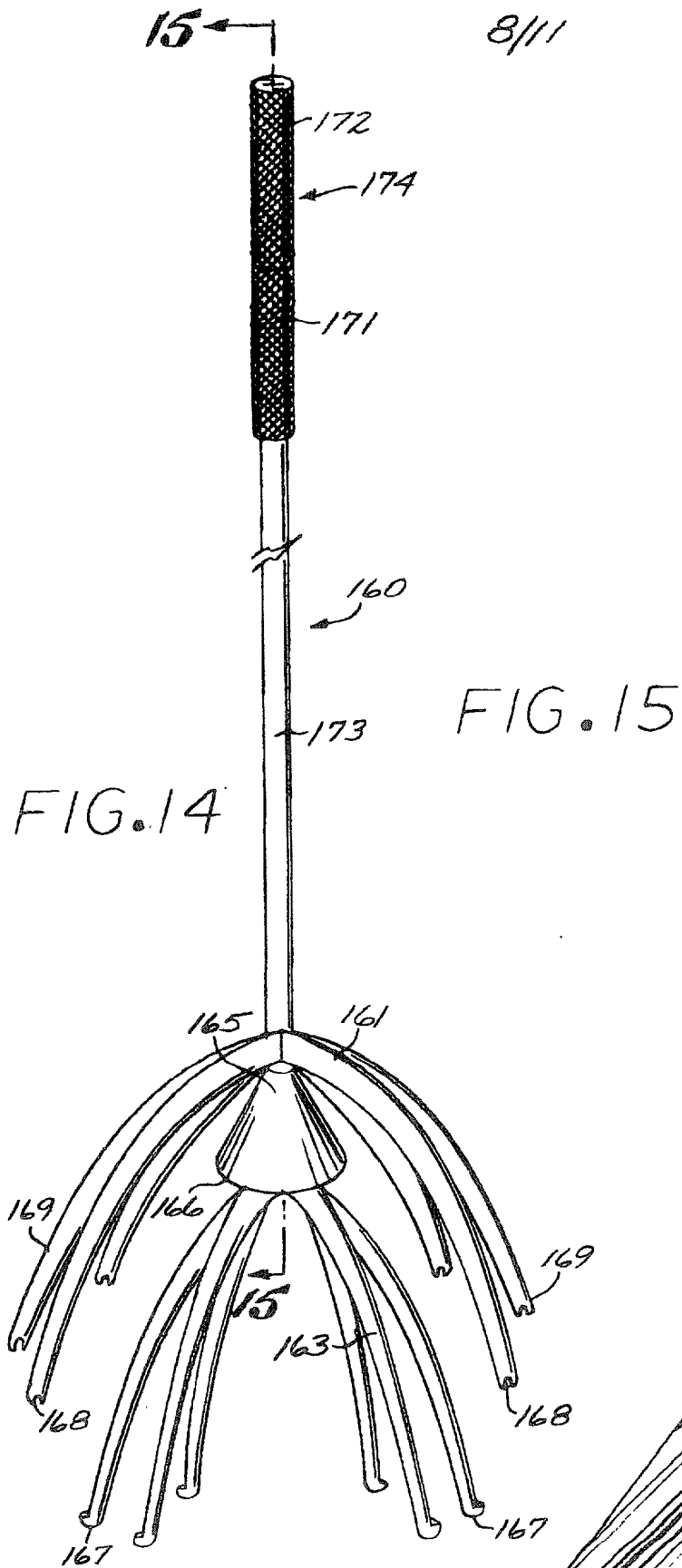


FIG. 16

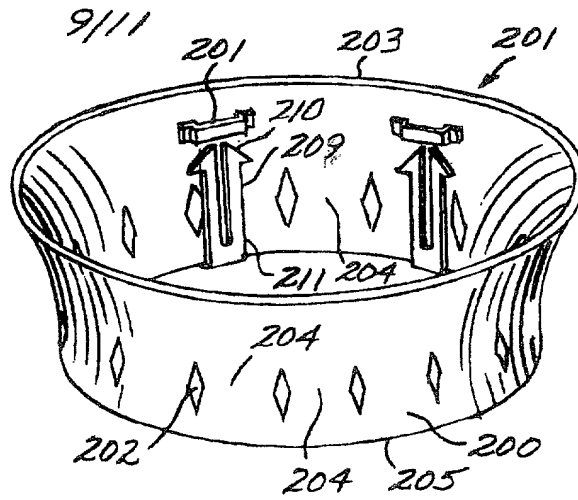


FIG. 17

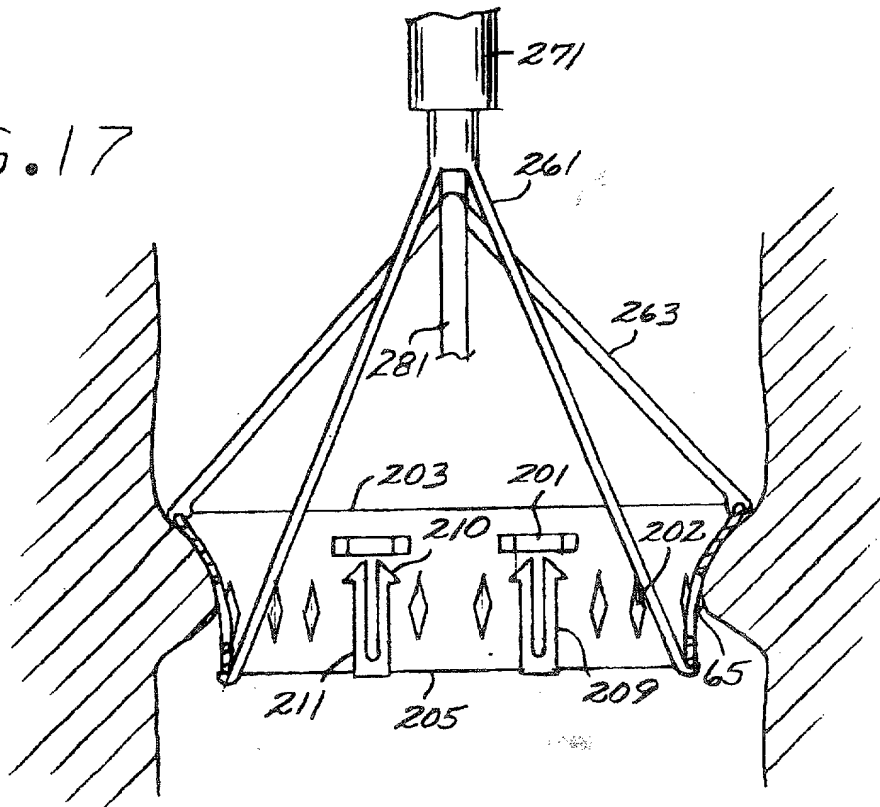
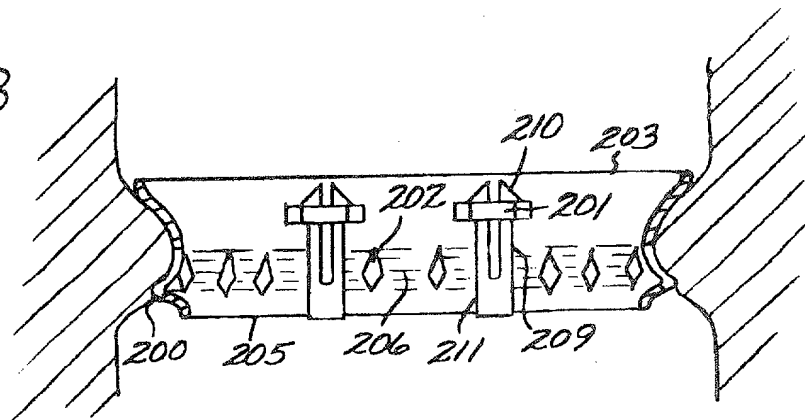


FIG. 18



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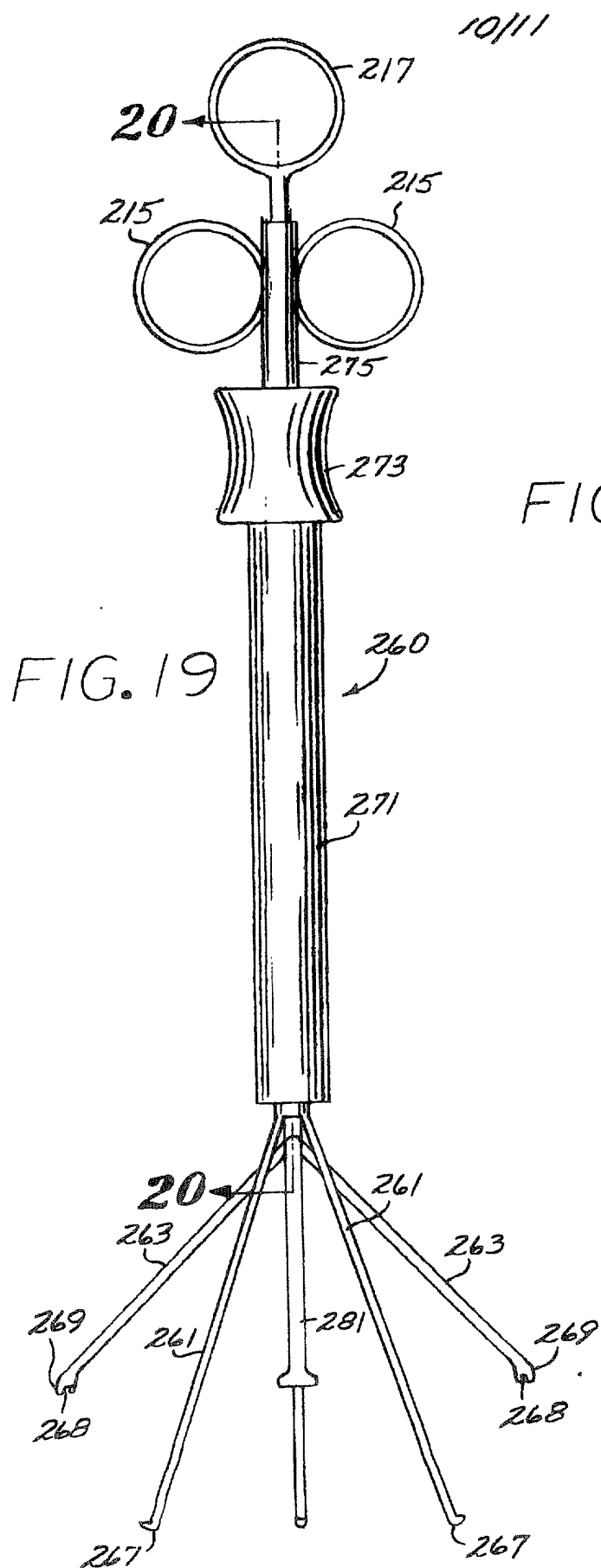
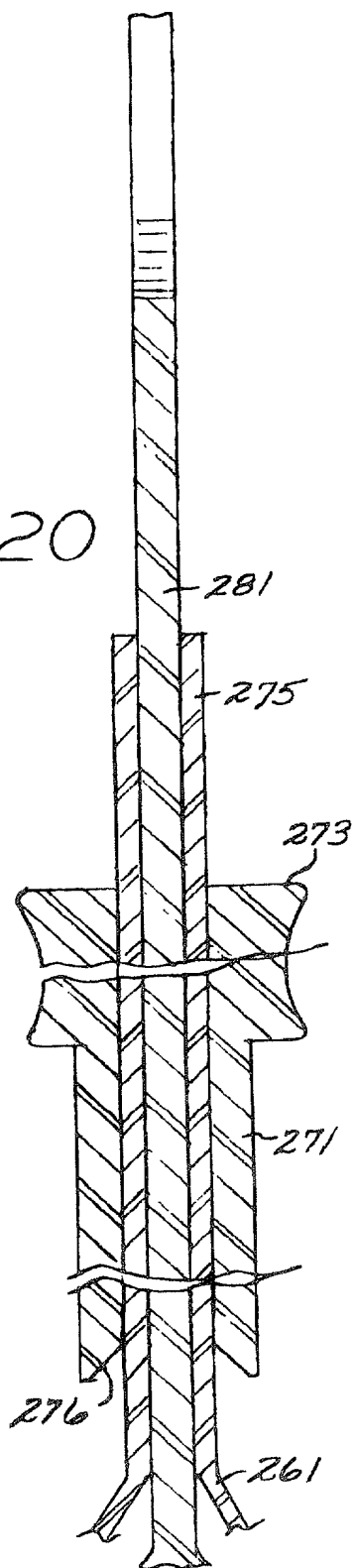


FIG. 20



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FIG. 21

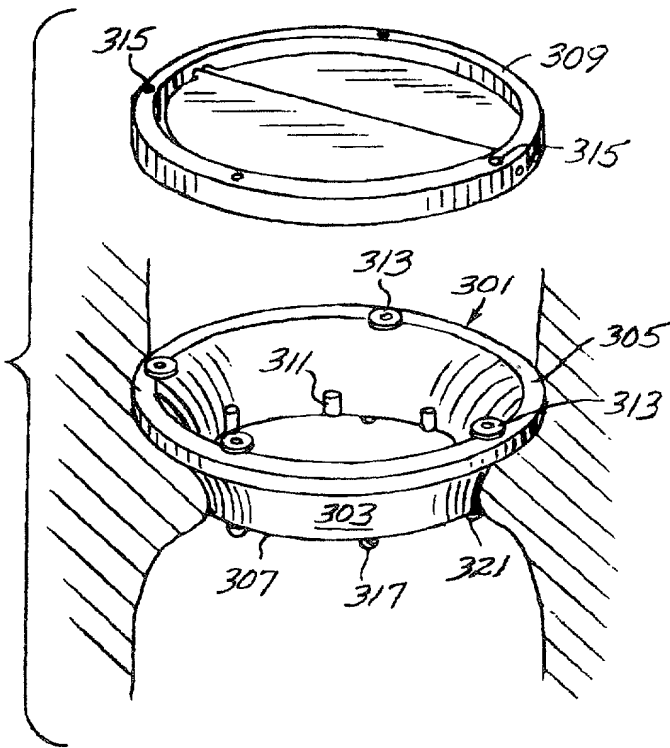
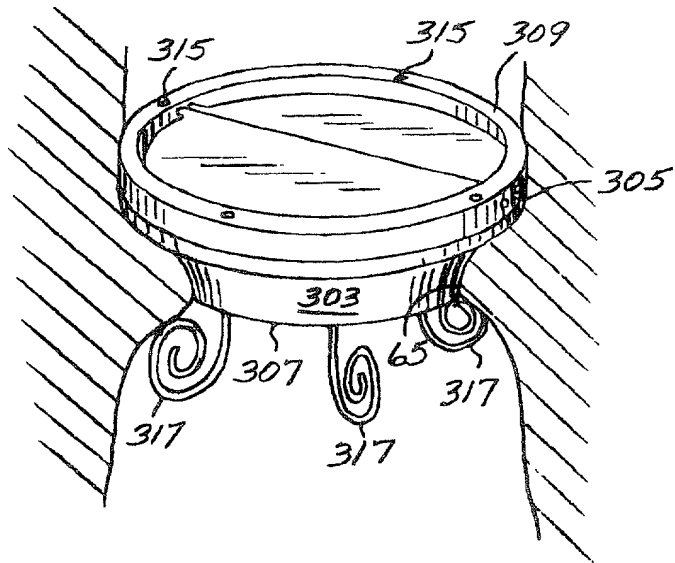


FIG. 22



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COMBINED DECLARATION AND POWER OF ATTORNEY

**(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,
CONTINUATION, OR C-I-P)**

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is for an original application.

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

HEART VALVE ANNULUS DEVICE AND METHOD OF USING SAME

SPECIFICATION IDENTIFICATION

The specification is attached hereto.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56.

09666617-092000

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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Francis A. Utecht	16,605
Gary M. Anderson	30,729
Gunther Hanke	32,989
Michael S. Doll	44,092
Craig McLaughlin	44,925

I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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562-432-0453

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE

John A. Macoviak

Inventor's signature

Date 9-14-00

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